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10/057,512	01/25/2002	Peter A. Courtage	399098	4328
30955	7590	02/12/2004	EXAMINER	
LATHROP & GAGE LC 4845 PEARL EAST CIRCLE SUITE 300 BOULDER, CO 80301			ROANE, AARON F	
			ART UNIT	PAPER NUMBER
			3739	
			DATE MAILED: 02/12/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/057,512

Applicant(s)

COURTNAGE ET AL.

Examiner

Aaron Roane

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 21,22,30-48,61 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20,23-29 and 49-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to the following patentably distinct species of the claimed invention: Species #1 characterized by figure 1, Species #2 characterized by figure 2, Species #3 characterized by figure 3 and Species #4 characterized by figure 4.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

Art Unit: 3739

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant's election with traverse of Species #1(as drawn to claims 1-62) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that all of the figures (or embodiments) have the features of the item 126 and the shapable housing in common. This is not found persuasive because figure 1 characterizes a system having only a single therapeutic device system connected to a single power control mechanism, figure 2 ("schematically depicts an enhanced system" see page 19, line 17 of specification) characterizes a plurality of single therapeutic device systems (100, 202, 204 and 206) connected to a single power control mechanism (126) that in turn is connected to other external devices (i.e., a pc, speaker, display, etc.), figure 4 ("depicts another embodiment" see page 19, line 19 of specification) characterizes a system having only a single therapeutic device system with an ovaloid housing with biofeedback sensors (414 and 416) connected to a single programmable controller (422). Figure 1 shows no sensors or that the power control mechanism (in figure 1) has a plurality of ports in which to connect other therapeutic device systems neither does it show that the power control mechanism is connectable to external devices. Also Similarly, the section of the summary of invention describing figure 1 does not disclose that the power control mechanism (in figure 1) has a plurality of ports in which to connect other therapeutic device systems, it does not disclose that the power control mechanism is connectable to external devices, nor does it disclose that the system maybe used with biofeedback sensors.

The requirement is still deemed proper and is therefore made FINAL.

Art Unit: 3739

Since the examiner deems Applicant's election is improper in that figures 1-5 "are interrelated" (see page 2, beginning of last paragraph), being interrelated however, is different from being the same species and in that claims that are drawn to non-elected species (figures 2-5) have been included, the examiner withdraws claims 21, 22, 30-48, 61 and 62 from further consideration. Applicant has elected species #1 characterized by figure 1 to which the examiner believes claims 1-20, 23-29 and 49-60 are drawn. **Therefore, ONLY CLAIMS 1-20, 23-29 and 49-60 will be considered.**

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the

- curable material in claim 4 (a thermosetting resin in claim 5), the material for altering flexibility in claim 6 (the casting modality in claim 7) correspond to different types of material for layer 104 (see specification, page 10, line 14 through page 11, line 18. These patentably different, structurally distinct materials must be shown or the feature(s) canceled from the claim(s).
- heat conductive material of claim 12 must be shown or the feature(s) canceled from the claim(s).

No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: line 9 contains the phrase “shape configuration.” The examiner suggests changing “shape configuration” to --shape— or --configuration--.

Claim 4 is objected to because of the following informalities: line 1 contains the phrase “wherein shapable.” The examiner suggests changing “wherein shapable” to -- wherein the shapable.—

Claim 5 is objected to because of the following informalities: on line 2 the phrase “a comprises” should be deleted.

Claim 20 is objected to because of the following informalities: on line1 change the phrase “to serve” to --adapted to serve--.

Claim 9 is objected to because of the following informalities: on line 2, the word “fro” should be changed to --for--.

Claim 60 is objected to because of the following informalities: line 5 contains the phrase “a shape configuration through.” The examiner suggests changing “a shape configuration through” to --a shape through— or --a configuration through--. Additionally, remove the last of the two periods at the end of the last line of the claim.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

Art Unit: 3739

international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 6-19, 23-25, 28, 29, 49-57 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Zharov (USPN 6,443,978 B1).

Regarding claims 1, 2 and 14, Zharov discloses a therapeutic device system comprising energy emitters in the form of light emitting diodes (LEDs) (1), a power grid (the array of LEDs is connected to a power source and therefore inherently a power grid is present), and a shapable housing ("flexible substrate" 19 in figure 3), see abstract, col. 1-6 and col.7, line 38 through col. 8, line 27 and figures 1, 2 and 3.

Regarding claims 6 and 7, Zharov further discloses a casting material (plaster 18) within the shapable housing, see col. 8, lines 16-26 and figure 3.

Regarding Claims 8 and 9, Zharov discloses the claimed invention, see claim 4.

Regarding claim 10, Zharov further discloses the plurality of electrodes for tissue stimulation, see col. 3, lines 12-24, col. 4, lines 42-53, and claims 1 and 29.



Regarding claims 11 and 12, Zharov discloses the claimed invention. Zharov discloses a wide variety of material used for a substrate that have a wide range of thermal insulative and heat conductive properties. As Applicant has not provided any substantive parameters qualifying a material as an insulator or heat conductor, the examiner interprets these terms as broad as possible.

Regarding claim 13, Zharov discloses the claimed invention, see col. 3, lines 55-67 and claims 1, 10 and 11.

Regarding claim 15, Zharov discloses the claimed adhesive (21), see col. 8, lines 16-26 and figure 3.

Regarding claims 16 and 17, Zharov discloses the claimed invention. The custom capability of the invention disclosed by Zharov is evident in the plaster material (18) layer that uniquely conforms to an individual's knee (wherein the knee comprises a joint), this unique conformability is interpreted as a custom basis. Additionally, Zharov discloses that the device may be used to treat varicose veins, which is a vascular compromise, see abstract.

Regarding claims 18 and 19, Zharov discloses the claimed invention. The generic nature of the invention disclosed by Zharov is evident in the sock substrate (9) that many or any individual(s) may use. The joint in this case being the ankle. Additionally, Zharov

discloses that the device may be used to treat varicose veins, which is a vascular compromise, see abstract.

Regarding claims 23-25 and 28, Zharov discloses the claimed invention. The power supply in the form of the battery is contained or disposed directly on the substrate (housing), see col. 3, lines 12-18. The connection between the power supply in the form of a battery and the energy emitters is inherent. Additionally, the shapable housing having an embedded power grid is also inherently disclosed.

Regarding claim 29, Zharov discloses the claimed invention. Zharov discloses a means (2) for regulating the output of the energy sources, see col. 2, lines 33-52, col. 3, lines 13-24 and figure 1.

Regarding claims 49-57, Zharov discloses the claimed invention. Zharov discloses that the device (16) treats "part of the neck and are employed to treat osteohondrosis and neuritis of the neck nerve." Part of the neck ~~is~~ comprises the spinal column. Vertebrae constitute part of the neck and consist of bone. Device (17) treats the breast. See col. 7, line 62 through col. 8, line 15 and figure 2. Zharov discloses that the device or devices treat various regions of the human body (living body) and/or the entire body (see figure 8A) and therefore inherently the treatment area includes the vascular system and lymphatic system. Zharov also discloses that the device may be used to treat and is adapted to treat "inaccessible internal concavities" (e.g., the rectum) which is interpreted

2/9/04

as soft-tissue, see col. 8, lines 57-65 and figures 6A and 6B. Zharov does disclose that the device comprises a control unit coupled to a commutation that “which provides the switching of the sources with different spectrum ranges and supplementary physiotherapeutic modules in accordance with a program given.” The examiner interprets this to mean “programmably configured.” Additionally, Zharov discloses in the abstract that the device is intended “to treat various extensive pathologies on the bioobject's surface including dermatology, cosmetology; the treatment of traumas, bruises, oedemas, varicose veins, blood therapy, treatment of infectious processes.”

Regarding claim 60, Zharov discloses a therapeutic device system comprising energy emitters in the form of light emitting diodes (LEDs) (1), a power grid (the array of LEDs is connected to a power source and therefore inherently a power grid is present), and a shapable housing (“flexible substrate” 19 in figure 3), see abstract, col. 1-6 and col.7, line 38 through col. 8, line 27 and figures 1, 2 and 3. Zharov further discloses the plurality of electrodes for tissue stimulation, see col. 3, lines 12-24, col. 4, lines 42-53, and claims 1 and 29. Zharov also discloses the method of providing therapy comprising the step of conforming to contours of the treatment area wherein the shapable housing is molded to self-retain a shape or configuration (see claim 4), activating energy sources consisting of LEDs or LEDs and TENS electrodes (see element 1 and the electrodes detailed in col. 3, lines 12-24, col. 4, lines 42-53, and claims 1 and 29) wherein the energy activation is inherent according to a therapeutic program (see col. 2, lines 33-51, col. 4, lines 54 through col. 5, lines 13 and claim 1).

Claims 1, 4 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Vreman et al. (USPN 6,596,016 B1).

Regarding claim 1, Vreman et al. disclose a therapeutic device system comprising energy emitters in the form of light emitting diodes (LEDs) (44), a power grid (the array of LEDs is connected to a power source and therefore inherently a power grid is present), and a shapable housing (12), see abstract, col. 6 and 7 and figures 1A and 2.

Regarding claim 4, Vreman et al. further disclose a flexible/shapable housing comprising a curable material ("urethane liquid may be cast around strips 22 and then cured until hardened."), see col. 7, lines 30-55 and figure 1A.

Regarding claim 20, Vreman et al. further disclose a device (60) fully capable of being used as a mattress pad or cushion, see figure 5.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Russell (USPN 6,290,713 B1).

Regarding claim 1, Russell discloses a therapeutic device system comprising energy emitters in the form of light emitting diodes (LEDs) (76), a power grid (the array of LEDs is connected to a power source and therefore inherently a power grid is present),

Art Unit: 3739

and a shapable housing (70), see abstract, col. 12, line 35 through col. 14, line 48 and figures 6-8.

Regarding claims 2 and 3, Russell further discloses a flexible/shapable housing comprising a flexible material in the form of a metal sheet (110), see col. 14, lines 1-30 and figure 8.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zharov (USPN

6,443,978 B1) in view of Prescott (USPN 6,454,791).

Regarding claim 26, Zharov discloses the claimed invention except for explicitly reciting that the battery is a conformable, flexible structural composition. Prescott discloses a light therapy device comprising a conformable/flexible body (1) and teach the use of a

Art Unit: 3739

flexible polymeric battery (26) so that it <sup>is</sup> flexibly compatible with the conformable/flexible body, see col. 7, line 54 through col. 11, line 52 and figures 1 and 2. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Zharov, as taught by Prescott, to provide flexibility to the battery so that the battery is flexibly compatible with the conformable/flexible body or substrate.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zharov (USPN 6,443,978 B1) in view of Mendes et al. (USPN 5,259,380).

Regarding claim 27, Zharov discloses the claimed invention except for explicitly reciting that a voltage regulator is operable for uniform distribution of electrical current to the energy sources. Mendes et al. disclose a light therapy device and teach the use of a voltage regulator (52) operable for uniform distribution of electrical current to the energy sources "for the purposes of operating an analog switch," see col. 6, lines 31-62 and figure 1. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Zharov, as taught by ~~X~~ Mendes et al., to use a voltage regulator operable for uniform distribution of electrical current to the energy sources "for the purposes of operating an analog switch."

Claims 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zharov (USPN 6,443,978 B1) ~~in view of being null and void~~.

Regarding claims 58 and 59, Zharov discloses the claimed invention except that Zharov fails to explicitly recite that the device is “physically and programmably configured” to treat “repetitive motion trauma selected from the group consisting of carpal tunnel syndrome, sports-induced fatigue, strains, and sprains of the living body” and/or to provide “prophylactic use against conditions selected from the group consisting of repetitive stress disorders, sports-induced fatigue, strains, and sprains of the living body.” However, Zharov does show that the device is used to treat a number of physical body regions and/parts. Zharov does disclose that the device comprises a control unit coupled to a commutation that “which provides the switching of the sources with different spectrum ranges and supplementary physiotherapeutic modules in accordance with a program given.” The examiner interprets this to mean “programmably configured.” Additionally, Zharov discloses in the abstract that the device is intended “to treat various extensive pathologies on the bioobject's surface including dermatology, cosmetology; the treatment of traumas, bruises, oedemas, varicose veins, blood therapy, treatment of infectious processes.” The device disclosed by Zharov, specifically the sock device (9), the knee device (19) and the glove device (33) could be used to treat carpal tunnel syndrome, muscle soreness and fatigue and ankle sprains. Zharov implies a sports use for the device, see col. 8, line 66 through col. 9, line 10. On the whole, the invention of Zharov is interpreted by the examiner as disclosing the physically configured and programmably configured requirements of the claimed invention. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to use the

Art Unit: 3739

invention of Zharov that is physically configured and programmably configured, as is well known in the art, to treat “repetitive motion trauma selected from the group consisting of carpal tunnel syndrome, sports-induced fatigue, strains, and sprains of the living body” and/or to provide “prophylactic use against conditions selected from the group consisting of repetitive stress disorders, sports-induced fatigue, strains, and sprains of the living body.”

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vreman et al. (USPN 6,596,016 B1) as applied to claims 1 and 4 above, and further in view of Zharov (USPN 6,443,978 B1).

Regarding claim 5, Vreman et al. disclose the claimed invention except for explicitly reciting that the shapable housing comprises a curable thermosetting resin. However, Zharov discloses a shapable housing comprising a plaster casting material, see col. 8, lines 16-26 and figure 3. Since Applicant asserts the equivalence of a shapable housing comprising plaster casting materials and a shapable housing comprising a curable thermosetting resin, see page 10, lines 20-22, the recitation of a shapable housing comprising a curable thermosetting resin is interpreted as an equivalent/alternative structural limitation to that of a plaster casting material. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Vreman et al., as taught by Zharov, to use a shapable housing comprising a



Art Unit: 3739

plaster casting material in order to provide an alternate way of shaping the shapable housing.

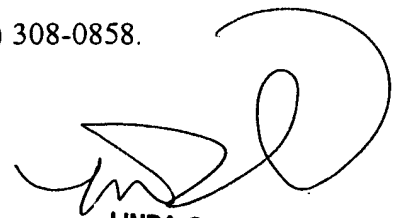
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A.R. *A.R.*  
January 27, 2004

  
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